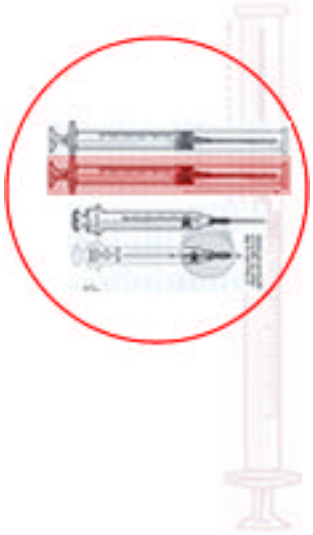
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



Phase 4: Evaluate Safer Medical Devices

Background

Our facility is a privately owned dental practice. We specialize in the care and treatment of pediatric and handicapped patients. We currently operate two offices, and employ approximately 30 people. Many of our staff members are part-time employees filling positions of associate dentists, dental hygienists, dental assistants and administrative staff.

Device Type

Our facility selected an injection device for evaluation. This device is specifically used for administration of local anesthetic. Because the device is used during direct patient care, it was evaluated by those staff members involved in patient care ("back staff") and those that potentially handle the instruments utilized (sterilization assistants). All of the dentists, dental hygienists and dental assistants were involved in the evaluation process and were asked to complete the evaluation form (attached) for dental safety syringes and needles.

Device Training

Our facility has regularly scheduled staff meetings with a high attendance rate. For that reason, we decided to utilize one of these meetings as a training session. The dentist involved as a member of the sharps prevention team agreed to provide the necessary training. During the training session, our objectives in finding a safer dental syringe and needle were explained to the staff members. The mechanics of the safety device were explained and then a mock demonstration of its use was completed. This demonstration actually took place in the treatment area of the office with both a dentist and an assistant working chairside. The demonstration of handling the device was then continued through to disposal of the product. Specifics such as the sterilization assistant's dismantling of the safety device and proper disposal of the sharps were reviewed. Unique features and do's and don'ts for the safety device were discussed. Many questions were asked and answered. All of the staff members were given the opportunity to individually handle the new device and ask any specific questions they may have had. The manufacturer of the safety device provided illustrations of proper handling of the device and they were posted in the treatment and sterilization areas. Before closure of the meeting, the attached evaluation forms were distributed and reviewed.

In order to allow for a learning curve, the staff members were asked to use the safety device for a **minimum** of ten times prior to evaluating the device. We chose a number of uses as a criteria vs. length of time (i.e., one month, one week) because many of our staff members are part-time employees. We also wanted to take into consideration vacations and scheduled leave.

Device Evaluation

The NIOSH sample evaluation form was used as a template in development of our evaluation form. We felt it was important to encourage individual comments and feedback from all staff members. Therefore, an area for such was designated on the evaluation form.

We felt that the evaluation process we developed was sufficient enough to determine the effectiveness of the safety device reviewed. Fortunately, the majority of our staff members were open to trying the new device and were very informative with their feedback. They were also willing to discuss any unexpected difficulties they encountered during the trial period. At times we (the dental assistant on the sharps prevention team) contacted the manufacturer of the safety device for feedback related to specific difficulties/shortcomings we were experiencing in using their device. Their input was very valuable and prompted many of the care providers to continue trial use of the product.

Initially, only a few evaluations where completed by the staff. However, with several reminders and requests for the evaluation forms we received responses from 100% of the dentists and roughly 75% of the auxiliary staff. Much of the feedback was positive, but there were two major concerns that prompted our termination of evaluation of the device. The first was the bulkiness of the safety device, which decreased visibility when used intraorally. The second was the visible differences in the needle itself. Although the needle was labeled as the same size as that which we previously used, it was visibly shorter and not as strong (too much flexibility). This prompted a safety concern for patients due to possible intraoral breakage of the needle. The general consensus was that the concept was good, but the device was not developed enough to completely replace our current device(s).

Lessons Learned

Overall, the evaluation process went well and our approach worked well for our facility. The open communication between staff members during the evaluation period was critical to the success of the process. Because of this, difficulties and concerns were addressed immediately and the trial period progressed more fluently.

Staff Hours and Costs
Phase 4: Evaluate Safer Medical Device(s)

Staff Hours:

Type of Staff	Hours Spent on Phase
Management (practice owner)	2
Administrative (non-clinical duties)	24
Front-line (clinical training & feedback)	20
Total	46

Other, non-labor items:

Item
1. printing/copying of materials
2. meeting facility space
3. lunch provided during training session
4. supply of safety device to be evaluated

Instructions
for
Evaluation Form

1. **Do not complete the evaluation form until you have utilized the new device a** minimum of 10 **times.**
2. **Be sure to complete the form in its entirety. If there is a question that does not apply to your use or exposure to the new device, leave it blank or draw a line through the responses.**
3. **It is important that you note your position, i.e.: sterilization assistant, chairside assistant.**
4. **Be objective with your responses. There is an area at the end of the evaluation for you to make note of any additional comments pertaining to the device. If you prefer you can also make notes in the margins of each question.**
5. **When you have completed the evaluation form, please leave it in _____'s mailbox.**

Our tentative deadline for completion of the evaluation form is_____. If you have any concerns about meeting this deadline please see _____.

All **"back staff" that will utilize this device should complete this form.**

EVALUATION FORM
DENTAL SAFETY SYRINGES AND NEEDLES

Date:_____

Product name/brand/company:_____

Your position:_____

1. Did you receive training in how to use this product? Y N

2. Did you feel the training you received was adequate? Y N
If not, why?_____
_____

Please answer only the following questions that apply to your duties and responsibilities. If a question does not apply to your duties and responsibilities, please leave it blank.

During pilot use of the device……	Strongly Disagree	Disagree	Agree	Strongly Agree
1. The device felt stable during assembly, use and disassembly.	1	2	3	4
2. The anesthetic cartridges were easy to change.	1	2	3	4
3. The syringe needles were easy to change during tx, when necessary.	1	2	3	4
4. The weight of the device during use was comfortable in comparison to the current syringe.	1	2	3	4
5. The device fit my hand comfortably during use.	1	2	3	4
6. Aspiration of blood into the anesthetic cartridge was easily preformed and clearly visible.	1	2	3	4
7. There was a clear view of the injection site and needle tip during use.	1	2	3	4

8. The device fit comfortably in patients' mouths.	1	2	3	4
9. I was able to use the piloted device as well as the conventional device.	1	2	3	4
10. The safety feature was easy to recognize and use.	1	2	3	4
11. The safety feature preformed reliably.	1	2	3	4
12. The safety device was easily be activated with one hand.	1	2	3	4
13. Activation of the safety device did not pose an increased risk of exposure.	1	2	3	4
14. The device was easily disposed of in currently used sharps containers.	1	2	3	4
15. The device is adequate and safe for clinical use.	1	2	3	4
16. I would be willing to use the device exclusively and eliminate my conventional device.	1	2	3	4
17. I do not need further training regarding use of the device.	1	2	3	4

Additional Comments (Please offer details related to any "strongly disagree" or "disagree" responses): _____
_____
_____
_____
_____
_____
_____